

Notice of Allowability	Application No.	Applicant(s)	
	09/857,402	AGUILAR RUBIDO ET AL.	
	Examiner	Art Unit	
	Bo Peng	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 6/11/07.
2. ☒ The allowed claim(s) is/are 43-46.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____ |
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DETAILED ACTION

1. The examiner of your application in the Patent and Trademark Office has been changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Bo Peng, Art Unit 1648.

2. This Office Action is in response to the reply filed June 11, 2007. Claims 15, 16, 21-23, 38, 39, 41 and 42 are pending.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. **(Prior rejection-withdrawn)** The rejection of Claims 15, 16, 21-23, 38, 39 and 41 under 35 U.S.C. 103(a), as being unpatentable over Milich *et al.* in view of Neurath *et al.* (U.S. Patent 6,319,501) and Chisari (U. S. Patent 5,932,224), **is withdrawn**.

5. **(Prior rejection-withdrawn)** The rejection of Claims 15, 16, 21-23, 38, 39, 41 and 42 under 35 U.S.C. 103(a), as being unpatentable over Milich, in view of Neurath and Chisari, and further in light of Carrano, **is withdrawn**.

EXAMINER'S AMENDMENT

4. An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

5. Authorization for this Examiner's Amendment was given in a telephone interview with Applicant's representative James Harrington on January 17, 2008.

6. Cancel Claims 15, 16, 21-23, 38, 39, 41 and 42.

7. Add new Claims 43-46 as set forth below:

Claim 43. An immunogenic composition comprising a mixture of:
(a) a first antigen which is Hepatitis B virus surface antigen (HBsAg), and
(b) a second antigen selected from the group consisting of Hepatitis C virus core antigen and a virus-like particle of Human Papilloma virus type 16,
wherein said HBsAg has an adjuvant effect on the second antigen, and wherein said first and second antigens are each present from 0.001mg to 1mg.

Claim 44. The composition according to claim 43, wherein the composition is suitable for nasal administration.

Claim 45. An immunogenic composition comprising a mixture of:
(a) a first antigen which is Hepatitis B virus surface antigen (HBsAg), and
(b) a second antigen and a third antigen, wherein the second and third antigens are selected from the group consisting of Hepatitis C virus core antigen, Hepatitis B core antigen (HBc) and a virus-like particle of Human Papilloma virus type 16, wherein the antigens are each present from 0.001mg to 1mg, wherein the HBsAg has an adjuvant effect on the second or third antigen.

Claim 46. A method for generating an immune response in a mammal comprising administering mucosally to the mammal an immunogenic composition, wherein the immunogenic composition comprises a mixture of:

- (a) a first antigen which is Hepatitis B virus surface antigen (HBsAg), and
- (b) a second antigen is selected from the group consisting of Hepatitis C virus core antigen, Hepatitis B core antigen (HBc) and a virus-like particle of Human Papilloma virus type 16,

wherein said HBsAg has an adjuvant effect on the second antigen, and wherein said first and second antigen are each present from 0.001 mg to 1 mg.

8. Claims 43-46 are pending and allowable.

The following is an Examiner's Statement of Reasons for Allowance:

9. Claims 43-46 are free of the prior art of the record. The Examiner is not aware of any teachings and suggestions in the prior art of the record that would point the artisan to the claimed the combined immunogenic composition of HBsAg with HCV core antigen, or with HPV-16 VLP; and to the combined immunogenic composition of HBsAg with the other two antigens consisting of HBV core antigen (HBc), HCV core antigen and HPV-16 VLP; and a method of inducing immune responses by using the claimed immunogenic compositions. Furthermore, the specification and the declaration of Mr. Julio Aguilar Rubido under 37 C. F. R. 1.132, filed on June 6, 2003, have shown unexpected results indicating that the first antigen HBsAg can enhance the immunogenicity of the second and the third antigens consisting of HBc, HCV core antigen and HPV-16 VLP when HBsAg is co-administered with them together. Accordingly, Claims 43-46 are allowed.

10. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The examiner can normally be reached on M-F, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, Ph.D. can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Bo Peng/
January 17, 2008



ZACHARIAH LUCAS
PATENT EXAMINER